K113818

MAR 2 1 2012

PULPDENT CORPORATION

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510(k) Summary

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ken@pulpdent.com

DEVICE:

Trade Name: ***Embrace™ WetBond™ Pit and Fissure Sealant, Low Fill***
Classification Name: Pit and Fissure Sealant and Conditioner
FDA Product Code: 76 EBC, 21 CFR Part 872.3765

PREDICATE DEVICES:

Pulpdent Embrace™ WetBond™ Pit and Fissure Sealant
Pulpdent Embrace™ Clear Sealant

DESCRIPTION:

Embrace Pit and Fissure Sealant, Low Fill is a fluoride releasing, light-cured acrylate resin, with no Bisphenol A, that is less than 10% filled and is available in two shades, tooth-colored and off-white.

INTENDED USE:

Embrace Pit and Fissure Sealant, Low Fill is used by dental professionals to seal the pits and fissures in teeth.

COMPARISON WITH PREDICATE PRODUCTS:

Embrace Pit and Fissure Sealant, Low Fill is substantially equivalent in design, composition, performance and intended use to the predicate products. The predicate products have been found substantially equivalent under the 510(k) Premarket Notification process as Class II Dental Devices under CFR 872.3765.

A summary of the comparison:

PRODUCT	DESCRIPTION	INTENDED USE	COMPOSITION
Embrace Pit and Fissure Sealant, Low Fill	Fluoride releasing, light cured, acrylate resins	Seal the pits and fissures in teeth	Acrylate resins Photo-chemistry
Embrace Pit and Fissure Sealant K020287	Fluoride releasing, light cured, glass-filled acrylate resins	Seal the pits and fissures in teeth	Acrylate resins Photo-chemistry Glass filler
Embrace Clear Sealant K052281	Fluoride releasing, light cured, acrylate resins	Seal the pits and fissures in teeth	Acrylate resins Photo-chemistry

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SUMMARY OF PERFORMANCE TESTING – Bench

The following test results demonstrate that *Embrace Pit and Fissure Sealant, Low Fill* performs as intended:

Density / Specific gravity	1.160 g / mL
Working time in ambient light	> 5 minutes
Light cure setting time	20 seconds
Depth of cure after 20 second light cure	1.88 mm
Film thickness	9 μm
Compressive Strength	33,120 ± 3000 p.s.i. / 228 ± 21 MPa
Diametral Tensile Strength	5,365 ± 300 p.s.i. / 37 ± 2 MPa
Film Thickness	9 μm

CONCLUSION:

From the above comparisons, the bench testing, a search of the relevant scientific literature and the organizational experience with Embrace resins, it can be concluded that *Embrace Pit and Fissure Sealant, Low Fill* is substantially equivalent in design, composition, performance and intended use to the predicate products. The predicate products have been found substantially equivalent under the 510(k) Premarket Notification process as Class II Dental Devices under CFR 872.3765 and have been used by dental professionals for more than ten years with no reports of adverse events.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 2 1 2012

Mr. Kenneth J. Berk
Director of Research
Pulpdent Corporation
80 Oakland Street
Watertown, MA 02472

Re: K113818
Trade/Device Name: Embrace™ Wetbond™ Pit and Fissure Sealant, Low Fill
Regulation Number: 21 CFR 872.3765
Regulation Name: Pit and Fissure Sealant and Conditioner
Regulatory Class: II
Product Codes: EBC
Dated: December 21, 2011
Received: December 30, 2011

Dear Mr. Berk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113818

Device Name: ***Pulpdent Embrace™ WetBond™ Pit and Fissure Sealant, Low Fill***

Indications For Use:

Embrace Pit and Fissure Sealant, Low Fill is a professional dental material, designed with no Bisphenol A, that contains fluoride releasing, light cured, glass-filled acrylate resins and is less than 10% filled. *Embrace Pit and Fissure Sealant, Low Fill* is available in two shades (tooth-colored and off-white) and is used to seal the pits and fissures in teeth.

Prescription Use _X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113818